In re Application of: Bobrowski, Paul J
Serial No.: 10/674,986
Raymond J.
Atty. Docket No.: PHMC0745-020

Art Group: 1614
Examiner: Henley III,

Amendment dated 6/11/2004
Reply to Office Action of March 15, 2004

Amendments to the Specification:

Please replace paragraph [009] with the following amended paragraph:

[009] In contrast to its immunostimulating alkaloids, preparations or decoctions of *Uncaria* plant material also exhibit an inherent immunosuppressive and anti-inflammatory result. This dichotomy between the immunostimulatory (pro-inflammatory) alkaloids and the immunosuppressive (anti-inflammatory) agents, concurrent yet opposing actions – stimulation and suppression – limit the true potential and benefits of either component. Thus, a method of distinguishing and removing from Uncaria decoctions the immunostimulatory alkaloids would result in an *Uncaria* extract with enhanced efficacy and therapeutic potential of the polar, immunosuppressive, TNF-alpha inhibiting agents. The present invention describes an extract and method for extracting **[[and then]]** or depleting from plants of the *Uncaria* species (Cat's Claw or Uño de gato) it's lipophilic, immunostimulating alkaloids whilst retaining and then further concentrating its polar, immunosuppressive agents. The process generally comprises an organic extraction(s) and drying of decocting crude *Uncaria* plant parts. The resulting *Uncaria* extract is substantially deplete of immunostimulatory actives and retains enhanced anti-inflammatory components and antioxidant capacities.

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Please replace paragraph [016] with the following amended paragraph:

[016] An organic solvent is subsequently added to the dried decoction or extract. A preferred organic solvent is chloroform/methanol (2:1) added in a volume-to-volume ratio of 1:1 to 1:20. Another suitable organic solvent is ethyl acetate. **The dried decoction and organic solvent are mixed and subsequently separated. One preferred manner of separating the polar constituents and alkaloids of the dried decoction involves exposure of the dried decoction to organic solvent. One convenient means of exposure comprises placement of the dried concoction into a sack or bag, constructed of paper cotton or other equivalent materials, and immersion in organic solvent. Following exposure, the bag is subsequently removed from the organic solvent and dried to eliminate any residual organic solvent. Drying resolves the genus Uncaria extract comprised of polar constituents and largely deplete of the alkaloids captured by the organic solvent. Drying and may be accomplished by one or more drying processes including heating, air drying, freeze drying or vacuum drying.** ~~**Following mixing and phase settling the organic layer is removed from the aqueous layer for further processing according to one aspect of the invention. The solutes contained within the aqueous extract are then resolved by one of several drying processes: heating, air drying, freeze drying or vacuum drying.**~~

Depletion of alkaloids content is confirmed by high performance liquid chromatography (HPLC) as indicated in Figure 1.